**NASA INSTITUTIONAL REVIEW BOARD (IRB)**

**CONSENT TO BE A PART OF A RESEARCH STUDY**

*[Insert study title]*

*[Insert eIRB STUDY number]*

**NOTE: Any alterations to this consent document will invalidate the test subjects’ consent unless the changes are approved in advance by the IRB.**

 **ABOUT THIS RESEARCH CONSENT FORM**

You may be eligible to take part in a research study.

A research study is carefully planned and designed to increase scientific knowledge.

This NASA IRB Consent form describes important information related to participation in a research study including the purpose, planned procedures, and potential risks.

Please take time to review this information carefully. Talk to the researchers about the study and ask any questions you have. **Make sure you fully understand what will be expected of you and the risks associated with participating in this study.** You may also wish to talk to others (for example, your friends, family, or doctors) about your participation in this study. If and when you decide to be a participant, you will be asked to sign this form and you will be given a copy.

Taking part in this study is completely **voluntary**. The decision to participate is yours. You may also leave the study at any time. If you leave the study before it is finished, there will be no penalty to you.

This NASA IRB Consent form provides a detailed description regarding essential information including, but not limited to, **how, when, where**, and **by whom** a signed informed consent will be obtained.

**Note: Failure to disclose pre-existing medical conditions may place you at greater risk for injury or other adverse events resulting from your participation in this study.**

**1. KEY INFORMATION**

* 1. What am I being asked to do? *[Describe the procedures participants will follow, duration, technology use, expectations -all organized in a way to facilitate understanding.]*
	2. What are the possible risks/discomforts? *[Describe foreseeable risks (physical and/or psychosocial) or state that risks are no more than those experienced in day to day life.]*
	3. What are the benefits for me? *[If any, please explain.]*
	4. Is there any compensation for my time? *[If yes, please explain.]*
	5. How will my information and/or identity be protected? *[Will data be identifiable/attributable? If so, for how long and who will have access? How will the data be stored and secured?]*
	6. Are there any alternatives to participation in this study? *[Describe any alternatives to participation*. *If none: state “the alternative to participation is to not participate”.]*

*[All above questions are to be included even if the answer is “no” or “n/a”]*

**2. GENERAL INFORMATION**

* 1. The study title is: *[Please insert study title here]*
	2. The Principal Investigator for this study is: (name, degrees, affiliations): *[Please insert name/degrees/affiliations here]*

2.3 This study is sponsored or funded by: *[Please insert sponsor/funder here]*

**3. PURPOSE OF THIS STUDY**

3.1 The purpose of this study is *[Briefly (1-2 sentences) explain the purpose/objectives of the research in simple words.]*

3.2 You are being asked to join this study because: *[state why the individual was selected, e.g., condition, age, or healthy volunteer.]*

**4. STUDY PARTICIPANTS**

* 1. In order to be eligible to participate, you may be asked to undergo the following screening tests or procedures:

*[Please insert pertinent screening tests for study inclusion here. If there are no screening tests or procedures, then type “not applicable.”]*

* 1. You are one of \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_subjects.

**5. STUDY PROCEDURES**

5.1 *Describe the procedures that participants will follow ORGANIZED IN A WAY TO FACILITATE BETTER UNDERSTANDING (using bullet points, pictures, diagrams, etc.) Please include:*

* *A detailed explanation of each test*
* *Data to be collected, including any audio/visual recordings (please outline whether participants may decline audio/visual recording and still participate)*
* *Equipment that will be used*
* *The amount of time each test will take and overall time of study participation*
* *An outline of which procedures are experimental*
* *Frequency of testing and whether it is continuous or intermittent*
* *A chart or calendar as a possible addition to the explanation of the tests*
* *Any need for follow-up examinations or tests*
* *The location of the testing*
* *The amount of blood, urine, saliva, or other biological samples and/or tissue that will be taken and how often*
* *Whether joining this study limits one’s chance to join other studies*
* *Describe which procedures are for research purposes, and*
* *A detailed list of any data that have been collected by other means that will be used by or shared with these researchers]*

5.2 The study you are joining includes one of the following categories:

[ ]   *“Randomized”* means that you are put into a group by chance (e.g., like flipping a coin). Neither you nor the principal investigator will choose what group you will be in. You will have a chance of being placed in any group.

[ ]   *“Blinded”* means you (blinded) will not know what group you are in.

[ ]   *“Double-Blinded”* means that neither you nor the Principal Investigator (double-blinded) will know what group you are in.

[ ]  *“Placebo”* means a pill with no medicine. In a placebo-controlled study, you may be given a study medication and it will contain either (name of drug) or placebo (pills with no medicine).

[ ]   *“Observational”* means a chart or record-based study that examines previously collected data.

[ ]  None of the above: [*please describe]*

**6. DRUGS, BIOLOGICS, and MEDICAL DEVICES**

6.1 Is a study drug or biologic used?

[ ]  No

[ ]  Yes, the study drug or biologic is \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_.

[ ]  This drug or biologic is FDA approved.

[ ]  This is an investigational drug or biologic, with the FDA IND number: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_.

6.2 Is a medical device used?

[ ]  No

[ ]  Yes, the study medical device is \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_.

[ ]  This medical device is FDA approved.

[ ]  This is an investigational medical device, with the FDA IDE number \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_.

[ ]  This device is IDE exempt as *[provide rationale/support].*

[ ]  This is an investigational non-significant risk device, with IRB approval for use. A document providing full and informed disclosure is provided for your review.

**7. INFORMATION ABOUT RISKS AND HAZARDS**

* 1. You are joining a study that is:

[ ]  “Minimal risk” means that the probability and magnitude of harm or discomfort anticipated in the research is not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

[ ]  “Greater than minimal risk” means that the probability and magnitude of harm or discomfort anticipated in the research is greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests, but that the risks of harm or discomfort are considered to be acceptable when weighed against the anticipated benefits and the importance of the knowledge to be gained from the research.

* 1. The risks/hazards of joining the study and the steps taken to protect against harm include:

 *[List risks/hazards to subjects associated with participation in the research. If unknown, please state that risks/hazards are currently unforeseeable. List, then, all steps taken to mitigate the outlined risks/hazards.*

*Please disclose appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject. If the only alternative is to not participate, that should be stated.*

*If your study includes pregnant subjects and/or women of child-bearing potential please include the risks to pregnant females and fetuses. If there are currently no known risks please add the following statement “Currently there are no known risks to a pregnant female and a fetus for this protocol. However, unknown adverse fetal events may occur, even in the absence of maternal symptoms.”]*

**8. TREATMENT, INJURY AND COMPENSATION INFORMATION**

8.1 Even though researchers have taken steps to minimize the risks, you may experience problems or side effects. In the event of physical injury resulting from this study, NASA will provide or cause to be provided, the necessary immediate action or treatment. NASA will pay for any claims of injury, loss of life or property damage to the extent required by the Federal Employees Compensation Act or the Federal Tort Claims Act. Your agreement to participate shall not be construed as a release of NASA or any third party from any future liability, which may arise from, or in connection with, the test procedures.

**9. BENEFITS INFORMATION**

9.1 *Outline the benefits of study participation for the participant as well as others.*

*If no direct benefit to the participant from his/her participation in this study, you may include “Participation in NASA studies generally result in no direct benefit to you as an individual. It is hoped that the information learned from this research study will help (include your study benefit).”*

**10. NEW FINDINGS**

10.1 If new information is obtained during the study after you have joined, you *[****will/will not****]* be informed. You may change your mind about continuing in the study. You may be asked to sign a new consent form that includes the new information.

*[If subjects will be informed, please include what information will be provided to subjects, by whom, when, and how.]*

**11. STUDY WITHDRAWAL and/or TERMINATION**

11.1 You may withdraw from the study at any time. If you decide to leave before the study is finished, please tell the investigator or study staff. Your refusal will be honored. In cases when the responsible physician’s opinion is that study termination could have undesired consequences for your health and/or the health of other subjects, you will be told if there could be any harm to you if you decide to leave before the study is finished. If you tell the researchers your reasons for leaving the study, that information will be part of the study record.

11.2 Your withdrawal or refusal to participate in the study will not result in any penalty or loss of benefits to which you are otherwise entitled.

11.3 If you decide not to join the study, you may be eligible to participate in other studies.

11.4 Researchers may need to stop your participation in the study even if you want to continue participation. Some examples of this scenario include: (Check applicable boxes)

[ ]  The researcher believes that it is not in your best interest to stay in the study

[ ]  There is any problem with following study related instructions

[ ]  There is any problem with following hospital, clinic, or laboratory policies and procedures

[ ]  There is any serious complication during the study

[ ]  There is inappropriate behavior

[ ]  The study is suspended or canceled

[ ]  The subject’s information is or becomes unusable for any reason

[ ]  Events beyond NASA’s control occur, for example: fire, explosion, disease, weather, floods, terrorism, wars, insurrection, civil strife, riots, government action, or failure of utilities

[ ]  Existing data reveal answers earlier than expected

**12. COST and FINANCIAL INFORMATION**

12.1 *[Please describe any costs or bills that result from participation in the study. If not, please state There are no costs or bills to you for participation in this study.]*

**13. PAYMENT and REIMBURSEMENT**

*[Include one of the following and delete the other]*

13.1 You will not be paid to participate in the study.

*OR*

 Some participants will be paid to participate in the study as follows:

* You will not receive payment if you are a NASA civil servant, other federal civil servant employee, contractor, or International Partner crewmember participating in ESA, JAXA, CSA, or NASA-sponsored studies.
* If you will be paid, you will receive *[Please describe how subjects will be reimbursed, including total dollar amount, pro-rating, and bonus payments].*

**14. DATA PRIVACY AND CONFIDENTIALITY**

14.1 *[Please describe the extent to which confidentiality of records identifying the subject will be maintained, if applicable. Outline who will have access to identifiable data and for how long. Also, describe storage and destruction of data procedures.]*

14.2 Your privacy and the confidentiality of data collected as a part of this research study will be protected from unauthorized disclosure according to applicable federal law.

14.3 If applicable, your protected health information may be used or shared with others during the research for your safety. This may include:

* Existing medical records;
* Video and photographic materials;
* New information created from study-related tests, procedures, visits, and/or questionnaires.

14.4 Your protected information may be used or shared by NASA offices of research oversight or quality assurance, medical monitors, and researchers for the reasons below:

* To conduct and oversee the present research;
* To make sure the research meets NASA requirements;
* To conduct monitoring activities (including situations where you or others may be at risk of harm or reporting of adverse events);
* To become part of your medical record, if necessary, for your medical care;
* To review the safety of the research.
* To support “NASA Clinical Summit” activities where clinical experts evaluate relevant medical and research data to recommend clinical practice guidelines specifically for astronauts. These data will not include names or other information that explicitly link the information to you.

14.5 Every effort will be made to maintain the confidentiality of your study records. There are many reasons why information about you may be used or seen by the researchers or others during or after this study. Examples include:

* The researchers may need the information to make sure you can take part in the study.
* NASA and other government officials may need the information to make sure that the study is done in a safe and proper manner. These agencies may include the Department of Health and Human Services (DHHS), the Food and Drug Administration (FDA), the National Institutes of Health (NIH), and/or the Office for Human Research Protections (OHRP) or other domestic or foreign government bodies if required by law and/or necessary for oversight purposes.
* The FDA may need to review the information if the study involves the use of an experimental drug or device.
* Safety monitors, medical personnel, or safety committees may review your research data, stored biospecimens, and/or medical records for the purposes of medical safety or for verification of research procedures.
* A data and safety monitoring board (DSMB) may oversee the research, if applicable.

• The results may be used by the research team and possibly be presented/published at scientific conferences and/or in an article, but would not include information that would identify you without your consent.

14.6 You have the right to withdraw your consent for the researchers to use or share your research data. The researchers will not be able to withdraw all the information that already has been used or shared with others to carry out related activities such as oversight, or to ensure quality of the study. To withdraw your consent, you must do so in writing by contacting the researcher.

14.7 You have the right to request access to your study records after the study is completed. To request this information, you must do so in writing by contacting the researcher.

14.8 If physiologic data (including but not limited to standard measures, laboratory data, psychological, or physiological measurements) are obtained from you for this study, they may become the property of NASA’s Life Science Data Archive. All federal regulations concerning the privacy and confidentiality of these data will be followed. Records stored in this archive will not include names, registration numbers, or other information that explicitly links the information to you.

14.9 After your private identifiers have been removed, the remaining information or biospecimens could also be used for future research studies or distributed to another investigator for future research studies without your additional informed consent.

**15. CONTACT INFORMATION**

15.1 You may contact the Principal Investigator to:

* Obtain more information about the study;
* Ask a question about the study procedures;
* Report an illness, injury, or other problem;
* Leave the study before it is finished;
* Express a concern about the study.

Principal Investigator: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Email Address: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Mailing Address: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Study Coordinator: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Email Address\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Mailing Address: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Telephone: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

You may express a concern about this study by contacting the NASA Institutional Review Board (IRB) listed below:

Office of Research Assurance: Research Integrity & Protection of Human Subjects

2101 NASA Parkway

Mail Code SA

Houston, Texas 77058

NASA-IRB@nasa.gov

Visit: <https://irb.nasa.gov/?p=irbContactInfo>

**16. RECORD of INFORMATION PROVIDED**

16.1 Your signature in the next section means that you have received copies of all of the following documents:

[ ]  This NASA IRB “Consent to be Part of a Research Study” document

[ ]  Other (specify): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**17. SIGNATURES**

Research Subject:

I understand the information printed on this form. I have discussed this study, its risks and potential benefits, and my other choices with \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_. My questions so far have been answered. I understand that if I have more questions or concerns about the study or my participation as a research subject, I may contact the study team. I understand that I will receive a copy of this form at the time I sign it and later upon request.

Signature of Subject: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Name (Print legal name): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

[ ]  **Check here if the study will NOT utilize video, audio or still photography**

**Research Subject Release for Video, Audio, and/or Photo:**

I understand that this study will utilize video, audio and/or still photography to analyze study results and I consent for the use of these materials.

 [ ]  I accept

 [ ]  I do not accept

Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Principal Investigator (or Designee):**

I have relayed detailed information to this subject about this study. I believe it to be accurate and complete. The subject has indicated that he or she understands the nature of the risks and benefits of participating in this study.

Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Title: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Witness (optional):**

I observed the above subject sign this consent document.

Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_